Legislative and Regulatory Aspects of Risk

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I. Introduction;

The application of risk assessment at the state level a unique problem due to the pressure for rapid timely decisions, immediacy of political factors and the roles of state agencies. This hour will explore risk assessment at the state level as it is currently conducted in a New England state, Connecticut.

First the state regulatory situation will be described showing that the risk assessment process follows the guidelines set forth in the federal programs. Perspective is provided as an overview of the process. This will be followed by discussion of three risk assessment problems currently under discussion, dioxin in air standard, drinking water standards and radon in water standards.

III. Perspective

A. Separation of management from risk assessment.

B. Unique role of Departments of Health.
1. Regulatory powers.
2. Interstate communication.

C. A differing view of uncertainty.

D. Myth of regulation,the Role of Good Science

1. It is believed that regulatory standards rest or should rest on on a scientific base. Thus if the regulations are good they must rest on good science. It follows from the above that effort needs to be expended to assure that regulations are scientifically defensible and credible to sustain pollution control decisions. (Paraphrased from former head of SAB)

2. There are several myths around regulations and the regulatory process. This is shown by the interaction of science with politics as it relates to three questions derived from the above and show that the level of misunderstanding is unacceptably high.

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3. Key questions about the process;

- a. Is bad science responsible for bad regulation?
- b. Would improved precision in science improve regulation?
- c. Have review boards improved the process from a public health perspective?

To reveal my bias at the outset I would answer NO to all of the above.

III. Background

A. Characteristics of "good science"

1. Controlled studies
2. Valid methods
3. Identification of test substances
4. Verification of conclusions

B. Characteristics of good regulation

1. Complete analysis of the data
2. Determination of limitations
3. Plausibility of the conclusions
4. Timely decisions

C. Nature of the problem

1. Items number 4 in A and B above are in conflict
2. Not to decide is to decide
3. Public health is not compatible with exposures while waiting to decide. eg ALAR , ASBESTOS, RADON

D. perceived conflicts in rights

1. Individual vs corporate rights
2. Articles IV and V of the Constitution
3. Economic realities

E. Examples of interactions of science and policy

1. Poor science and good policy
   Chloridane

2. Poor science and poor policy

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Asbestos
Alar

3. Good science and poor policy

Ethylene dibromide
Benzene

4. Good science and good policy

Methylene chloride
Most OP pesticides
Radon

F. Illustration of the need for risk assessment.

1. The typical environmental exposures.

2. The typical research protocol

3. Application of data to reduce uncertainty

IV A state's approach to ground water contamination.

The assessment and mitigation of groundwater contamination which affects private drinking water is one of the most difficult problems facing the health and environmental agencies at the state and local levels.

A primary aspect of the problem is the need to make an immediate decision to terminate potential exposures even though the contaminants, their actions and the levels of exposures are not known. It is also important to acknowledge that water is essential for habitability of the home.

This leaves the health official with need to make a decision with less than complete information. As a matter of principle these decisions should be health based and must be protective of public health. The decisions should also be defensible in the scientific sense.

There is a fundamental difference in the goals of academic research and the need to reach a policy position. An academic researcher who is faced with

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incomplete data correctly refuses to decide but waits for more data but this is a decision a public health official needs to decide because to wait is a decision in it self.

The decision needs to have the following characteristics it must be protective of the public health it must be timely, it should be accurate and it should comply with the regulations.

If there is no regulation the basis for these decisions is the general powers of the commissioner to protect the public health. This was not working in connecticut so the state set up a procedure for handling the situations

It is important to also understand the scope of the problem. Over the last ten years Connecticut has had over 1400 wells contaminated. These wells served 300,000 people. Under these circumstances it is not possible to Handle individual instances with a risk assessment approach.

A joint program has ben developed betweeen the departments of health services and the Departments of environmental protection. Within Health Services the process involves two groups the toxic hazards section which is responsible for risk assessment and the water supplies section which is responsible for correcting the problem.

The process is based on a statute within the Dept of environmental protection. The bottled water law.

V. The state Dioxin standard
    A. Criteria for standard
    B. Legislatures role.

VI. The water radon standard
    A. Background radon data
    B. Effect of the strict standard setting process

VII. Summary.

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